

# **Advanced Development of Chem-Bio Medical Countermeasures for the DoD**

Presented To  
**Armed Forces Epidemiology Board**

**March 22, 2005**

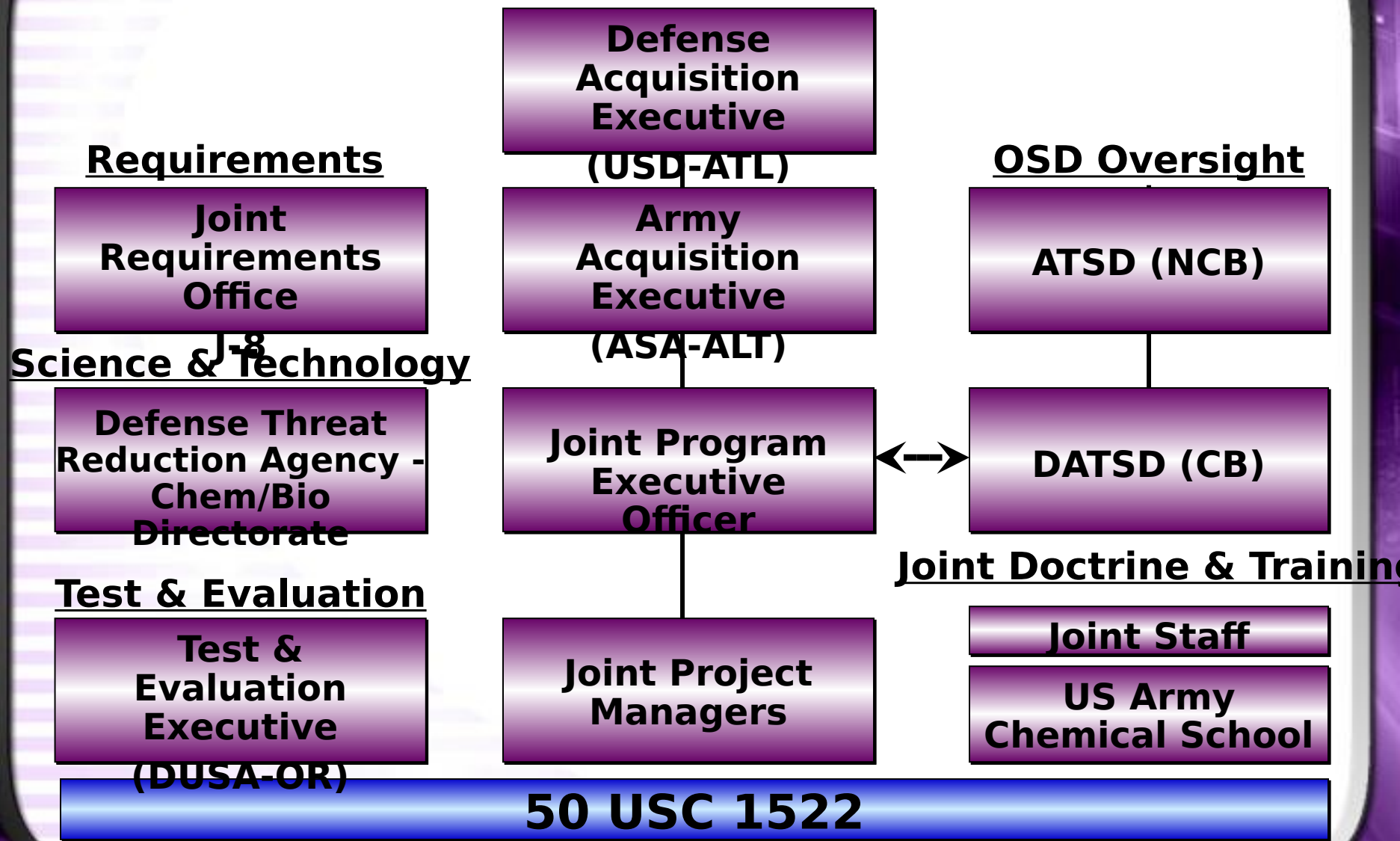
**Colonel Stephen B. Berté, Ph.D.**  
**Joint Project Manager**  
**Chemical & Biological Medical**  
**Systems**  
**[stephen.berte@us.army.mil](mailto:stephen.berte@us.army.mil)**

# Agenda



- **Organization**
  - **Chem Bio Defense Program**
  - **Chemical Biological Medical Systems (CBMS)**
- **Challenges in DoD Medical CBD Acquisition**
- **Joint Vaccine Acquisition Program (JVAP)**
- **Medical Identification and Treatment Systems (MITS)**
- **Conclusion**

# Chem/Bio Defense Program Acquisition Organizations



# System of Systems Approach to Counter the Threat



*Sustained Combat Power*



**Medical Pretreatment**



**Contamination Avoidance and NBC Battle Management (Detection, Identification, and Assessment)**



**Individual & Collective Protection**



**Installation Force Protection**



**Medical Treatment**

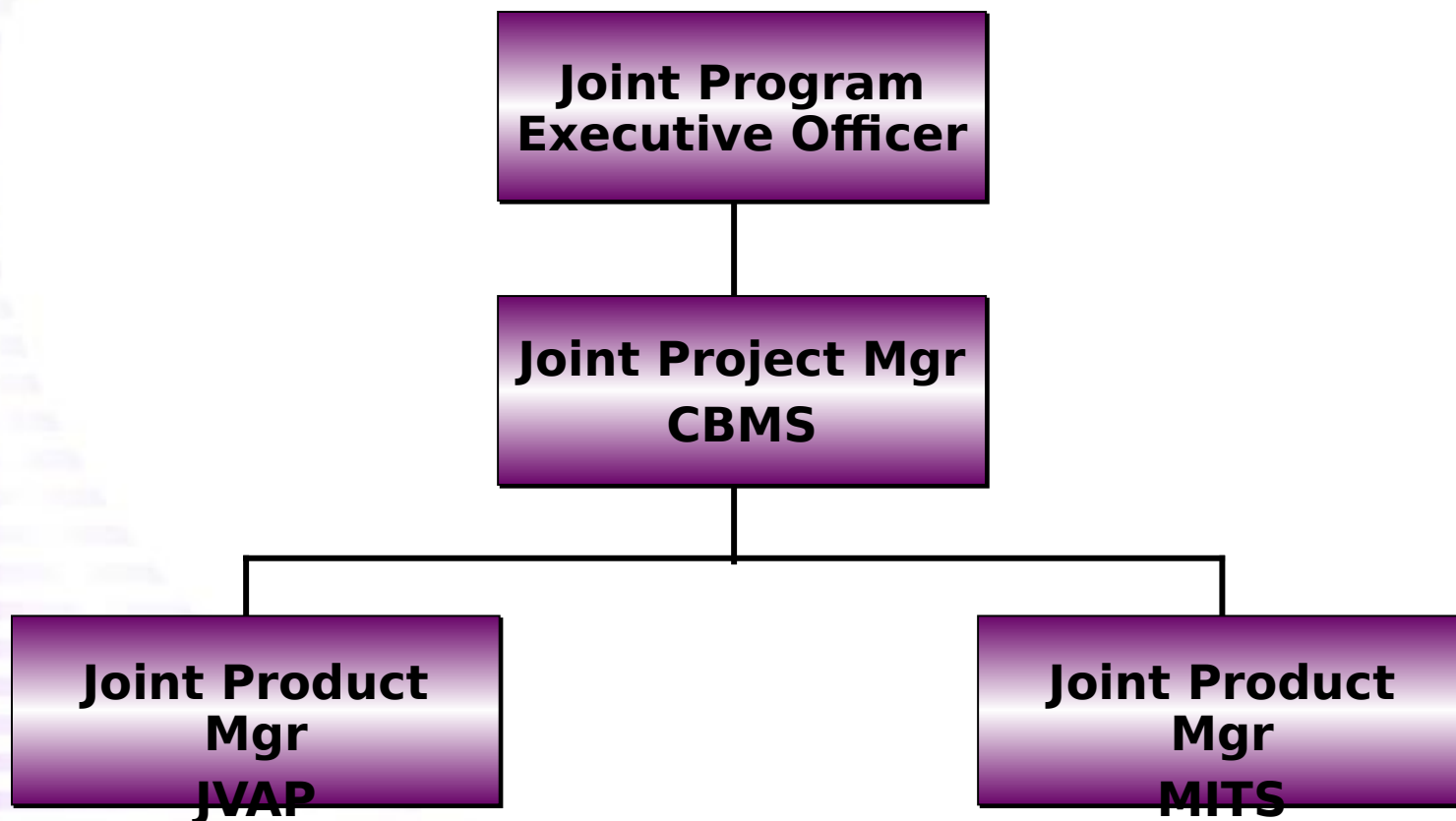


**Information Systems**



**Decontamination, Restoration**

# Chemical Biological Medical Systems (CBMS)



# CBMS Mission



**Develop, procure, field, and sustain premier medical protection and treatment capabilities against chemical and biological warfare agents.**





- Addresses user requirements based on Chairman of the Joint Chiefs of Staff priorities
- Develops FDA licensed chemical and biological defense (CBD) medical products
- Leverages international partnerships, other government agencies, and industry
- Manages product line within available resources
  - Funds product development efforts to minimize schedules
  - Expands or contracts product line based on available funding

# Industry Standard

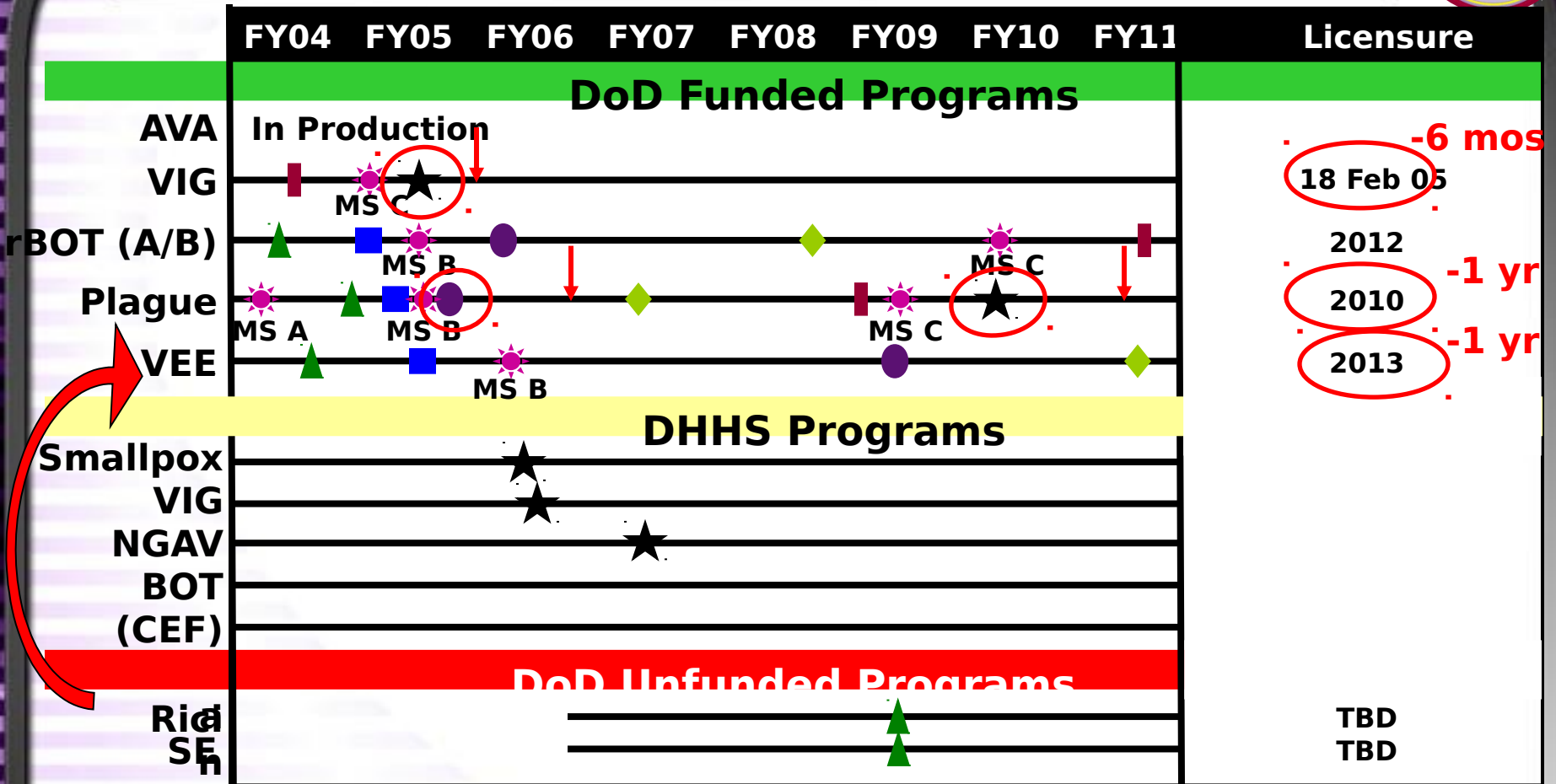
- **Industry trend:**
  - **Clinical trial development times are increasing**
  - **4 yrs in early 1990's to 6+ years in early 2000's**
- **CBMS projected clinical trial development times are:**
  - **Botulism vaccine = 6 yrs (FDA Licensure: FY12)**
  - **Plague vaccine = 5 yrs (FDA Licensure: FY10)**
  - **Advanced Anticonvulsant System = 7 yrs (FDA Approval FY11)**
- **CBMS schedules are in line with industry standard**
- **CBMS continues to explore ways to shorten schedules**

# JVAP Mission

**Aggressively develop, produce, and stockpile FDA licensed vaccine systems to protect the Warfighter from biological agents.**



# JVAP: Meeting Warfighter Needs

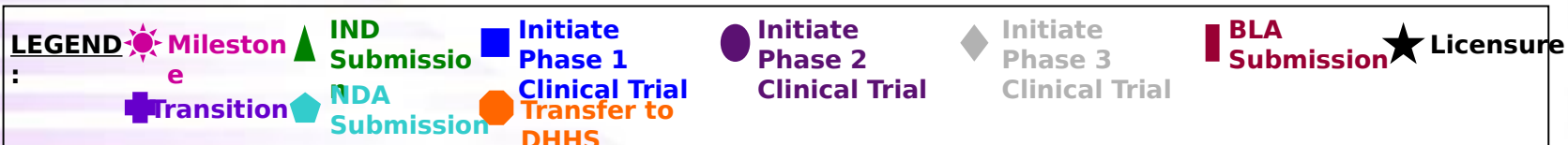
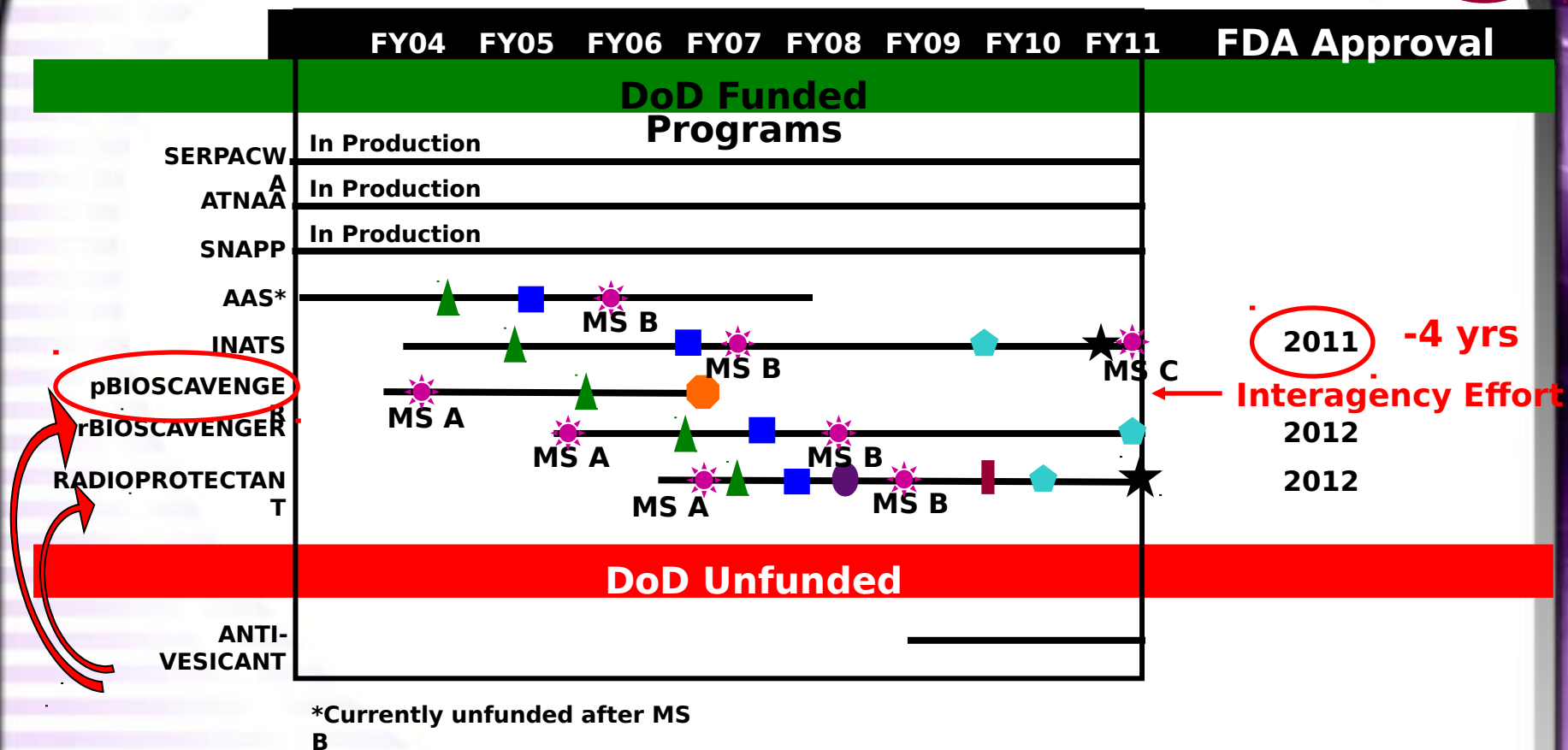


Highlights show FY04-FY05 changes

**Develop and acquire safe, effective, and FDA-approved products for prophylaxis, treatment, and diagnosis of chemical and biological warfare agent exposure.**



# MITS: Meeting Warfighter Needs



Highlights show FY04-FY05 changes

# DoD Medical Chem-Bio Projections



## FY05

- VIG: FDA licensure - Feb 18, 2005
- Plague & VEE: Submission of INDs & initiate Phase 1 clinical trials
- Plague: Initiate Phase 2 clinical trial
- pBioscavenger: award process development, small-scale manufacturing, acute toxicology studies, and a Phase 1 clinical trial contract
- rBOT: Milestone B decision
- JBAIDS: LRIP and Initial Operational Capability

## FY06

- Plague: Continue Phase 2 clinical trial
- VEE: Complete Phase 1 clinical trial; Milestone B decision
- rBOT: Initiate Phase 2 clinical trial
- rBioscavenger: Milestone A decision
- JBAIDS Block II: Milestone B decision

# Take Aways

- **CBMS program addressing DoD priority requirements**
  - **Focused on FDA licensure**
  - **Working within available resources**
  - **Leveraging Other Government Agencies and International partners**
- **CBMS acquisition strategy is in line with industry schedule standards for achieving medical product licensure**
- **CBMS continues to look for and find ways to shorten developmental schedules.**

***COL Stephen B. Berté***

**Joint Project Manager, CBMS**

**301-619-7400**

**[stephen.berte@us.army.mil](mailto:stephen.berte@us.army.mil)**